REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Claims 12 and 13 have been amended to state that the active ingredient is selected from the group consisting of voglibose, candesartan cilexetil and pioglitazone hydrochloride. This amendment is supported by original claims 15, 16 and 17. Claim 33 has been amended to delete "manidipine hydrochloride".

Claims 12-13 and 34-39 are rejected under 35 USC as obvious over WO 90/46215. This ground of rejection is deemed to be overcome as applied to the amended claims.

The cited reference fails to disclose or suggest the specific active ingredients of claims 12 and 13 as amended. Accordingly it is respectfully submitted that the cited reference fails to make obvious the claimed invention.

Claim 33 is rejected under 35 USC 103 as unpatentable over WO 90/46215 in view of U.S. 6,923,988. This ground of rejection is respectfully traversed as applied to claims 12-13 and 33-39.

Page 4 of the Official Action states that the Applicants' Rule 132 Declaration filed on September 19, 2006 is insufficient to overcome the rejection of claims 12-13 and 33 because:

"1. Examples 2-4 recite only particle size of 45 microns (see page 2 of the Declaration).

2. Examples 2-4 do not recite particle size of 130 microns. This is also true for example 8. There is no particle diameter of 130 microns in example 8 (see page 2 of the Declaration).

3. Examples 5-7 do not recite particle size of 130 microns (see page 2 of the Declaration).

4. Examples 10-12 and 14-15 recite large particle size and the particle size mentioned at page 2 of the Declaration correspond to sugar alcohols that are pulverized. None of the claims recite that the sugar alcohols are pulverized.

5. All the examples are specific to active ingredient. Claims 12-13 do not recite active ingredient.

6. Therefore, the results are not commensurate with the scope of particle diameter of the sugar alcohols."

Responsive to items 1-2, Examples 2-4 do recite a particle size of 130 μm.

Example 1 on page 28, lines 20-22 of the specification describes the use of D-mannitol obtained from Towa Chemical Industry Co., Ltd., product name Mannit S, having a "mean particle diameter of 130 μm".

Mannit S was used in Example 2, in combination with D-mannitol having a mean particle diameter of 45 μm. Please see line 25 on page 29 and line 1 on page 30 of the specification. The same combination was used in Example 3, referring to page 31, lines 1-2 of the specification. The same combination was used in Example 4, referring to page 32, lines 2-3 of the specification.

Thus, it is apparent that Examples 2-4 do include a combination of D-mannitol having mean particle diameters of 45 and 130 μm. Similarly, Example 8 describes a combination of 80 μm and 130 μm. See page 34, lines 17-18 and page 35, lines 3-4.

Regarding item 3, Example 5 describes the use of Mannit S at page 32, lines 19-20 of the specification. Similarly, Example 6 describes the use of Mannit S on page 33, lines 12-13 of the specification. Example 7 describes the use of Mannit S on page 34, lines 5-6 of the specification.

Thus it is apparent that Examples 5-7 use Mannit S having a particle size of 130 μm, based upon the teachings of Example 1.

Regarding item 4, it is respectfully submitted that a requirement that sugar alcohols be pulverized is unnecessary. The instant claims require that the mean particle diameter of the saccharide or sugar alcohol be in the range of 30 μm to 300 μm. Please note that claims 37-39 require the sugar alcohol to be pulverized.

Regarding item 5, the unexpected effect of the present invention is not dependent upon the use of any particular active ingredient. See pages 9-15 of the specification. Nevertheless

claims 12, 13 and 33 now require that the claimed quickly disintegrating solid preparation comprises an active ingredient which is selected from group consisting of voglibose, candesartan cilexetil and pioglitazone hydrochloride.

Regarding item 6, it is respectfully submitted that the results of the Declaration are commensurate with the scope of the particle diameter of the claimed saccharide or sugar alcohol. The examples described in the Declaration contain 15 examples of quickly disintegrating solid preparations using a saccharide or sugar alcohol with a mean particle diameter of between 43 μm and 185 μm.

It is respectfully submitted that the showing of unexpected properties supports the claimed range of a mean particle diameter of 30 μm to 300 μm. Moreover the showing clearly supports the narrower range of claims 34-36 which require the mean particle diameter of the saccharide or sugar alcohol is between 35 to 200 μm.

Furthermore, the showing clearly supports the narrower range of new claims 40-42 which require the mean particle diameter of the saccharide or sugar alcohol is between 43 to 300 μm.

In view of the foregoing, the preparations of Examples 1 to 15 have been shown to have unexpectedly improved:

(a) fluidity during tabletting,

(b) binding property and

(c) adhesion to punch,

as compared with the preparations of Comparative Examples 1 to 3. Thus, Table 1 clearly shows that an intraorally quickly disintegrating solid preparation have unexpectedly excellent properties using a saccharide or sugar alcohol with a mean particle diameter of 30 μm to 300 μm.

The Examiner states that absent a showing the criticality of the claimed range of the sugar alcohols, the claims are rendered *prima facie* obvious over WO document.

However, Table 1 of the present specification clearly chows the criticality of the mean particle diameter of the sugar alcohols. That is, the preparations of Examples 1 to 15 are those using saccharide/sugar alcohols having mean particle diameter of 30 μm to 300 μm and the preparations of Comparative Examples 1 to 3 are those using sugar alcohols having mean particle

diameter of less than 30 μm. As seen from Table 1, the preparations of Examples 1 to 15 have improved (a) fluidity during tabletting, (b) binding property and (c) adhesion to punch as compared with the preparations of Comparative Examples 1 to 3. Thus, Table 1 clearly shows that an intraorally quickly disintegrating solid preparation according to the claimed invention having excellent properties can be obtained by using a saccharide or sugar alcohol with a mean particle diameter of 30 μm to 300 μm without any problem in productivity.

For the Examiner's reference, the mean particle diameter in the Examples and Comparative Examples are summarized below.

Example and Comparative Example Nos.	Saccharide/sugar alcohol	Mean particle diameter (μm)
Example 1	D-mannitol	130
Example 2	D-mannitol	45 and 130
Example 3	D-mannitol	45 and 130
Example 4	D-mannitol	45 and 130
Example 5	D-mannitol	130
Example 6	D-mannitol	130
Example 7	D-mannitol	130
Example 8	lactose/D-mannitol	80 and 130
Example 9	trehalose	44
Example 10	trehalose	185
Example 11	erythritol	178
Example 12	xylitol	135
Example 13	maltitol	181
Example 14	erythritol	75
Example 15	sorbitol	43
Comp. Example 1	D-mannitol	21
Comp. Example 2	D-mannitol	21
Comp. Example 3	trehalose	19

In view of the above, it is clear that the reference does not suggest the unexpected criticality of the mean particle diameter of the sugar alcohol in the resulting properties of the quickly disintegrating solid preparation.

The Examiner states that the Declaration contains no data with respect to the lower endpoint for mannitol of 30 microns.

There is no requirement for a patent applicant to submit data for endpoints. The requirement is to submit data commensurate in scope with the claimed invention. It is respectfully submitted that the Declaration is commensurate in scope with the claims.

The Declaration compares examples of the invention having a mean particle diameter of 43 microns possessing the unexpected features of the invention, with comparative examples outside the invention having a mean particle diameter of 21 microns lacking the features of the invention. It is respectfully submitted that this is a sufficiently close comparison at the micron level to support the lower claimed endpoint of 30 microns. Nevertheless please note new claims 40-42 require a lower endpoint of 43 microns.

The Examiner states that the Declaration contains no data for lactose. It is respectfully submitted that no data for lactose is necessary.

Initially, it is noted that lactose is an ingredient with mannitol in Example 8. Therefore there is data for lactose.

Moreover the Examples of the Declaration contain data for 7 different saccharides/sugar alcohols. Given the similar structures and characteristics of the saccharides and sugar alcohols, one skilled in the art can reasonably expect that lactose will possess the same characteristics and properties of the 7 other saccharides and sugar alcohols which are tested in the Declaration.

Nevertheless new claims 43-45 exclude lactose.

In view of the foregoing, it is respectfully submitted that the claims as amended are patentable and nonobvious over the prior art, and allowance is solicited.

Respectfully submitted,

Kazuhiro OHKOUCHI et al.

By: Warcheek

Warren M. Cheek
Registration No. 33,367
Attorney for Applicants

WMC/dlk
Washington, D.C. 20006-1021
Telephone (202) 721-8200
Facsimile (202) 721-8250
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